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THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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CIVIL ACTION NO.

JUDGE

COMPLAINT

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and

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Plaintiffs,

v.

Cephalon, Inc.,
41 Moores Road
Frazer, PA 19355;

and

Teva Pharmaceuticals Industries, Ltd.,
5 Basel Street
P. O. Box 3190
Petach Tikva 49131, Israel;

and

Teva Pharmaceuticals USA, Inc.,
1090 Horsham Road,
P. O. Box 1090
North Wales, PA 19454;

and

Barr Pharmaceuticals
225 Summit Avenue
Montvale, NJ 10970

Defendants

COMPLAINT

The States and Commonwealths of New York, Ohio, Vermont, Indiana, Minnesota, Alabama, Alaska, Arizona, Arkansas, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, Wisconsin, Wyoming and the District of Columbia (collectively "Plaintiff States") by their Attorneys General, and Office of Attorneys General, on behalf of and/or for the benefit of their respective citizens and government agencies, allege the following unlawful conduct ("Complaint") against defendants Cephalon, Inc., ("Cephalon"), Barr Laboratories, Inc. ("Barr"), Teva Pharmaceutical Industries, Ltd., and Teva Pharmaceuticals USA, Inc. (both "Teva") (collectively "Defendants").

I. NATURE OF THE ACTION

1. Plaintiff States seek damages and equitable relief due to Defendants' unlawful anticompetitive conduct to delay generic competition for Modafinil, a drug indicated for the treatment of certain sleep disorders, including narcolepsy, which was and is sold by Defendant Cephalon under the brand name Provigil®.

2. Provigil was an unexpected "blockbuster" drug, achieving annual sales of more than a billion dollars despite being initially approved by the Food and Drug Administration ("FDA") for a rare "orphan" disease. Provigil was Cephalon's most

successful drug, accounting for more than half of its total sales in 2008. Provigil's commercial success invited strong interest from generic competitors, several of which were expected to obtain FDA approval and launch in 2006. To extend its Provigil monopoly profits beyond its lawful exclusivity period, Cephalon engaged in anticompetitive conduct. Rather than compete on the merits after its FDA-granted exclusivity expired in December 2005, Cephalon took anticompetitive measures to delay generic competition for several years, during which time it continued to reap monopoly profits for Provigil.

3. To delay generic competition, Cephalon knowingly enforced an invalid patent on generic competitors that it obtained due to its material omissions and misrepresentation to the Patent & Trademark Office ("PTO"). Despite knowing that the patent was invalid and fraudulently procured, Cephalon filed patent infringement litigation against each and every company seeking to manufacture generic Provigil. Although the infringement suits were baseless, Cephalon knew that merely initiating patent infringement litigation would significantly delay generic entry.

4. Cephalon was able to further extend its Provigil monopoly profits by settling each of the infringement actions, and including in each settlement an agreement to delay generic entry until no earlier than April 2012. In return for their agreement to delay generic entry, each generic competitor obtained a large and unjustified payment. In total, Cephalon compensated generic competitors an excess of $200 million for their "reverse payment" agreements to delay generic competition.

5. Cephalon's plan worked. Due to the anticompetitive settlement agreements,

generic competition did not commence until April 2012 – giving Cephalon six additional years of monopoly profits. And Cephalon shared a part of these additional profits with the generic competitors in exchange for their agreement to delay the launch of their generic Provigil.

6. Had Defendants competed on the merits and not illegally delayed generic competition until 2012, Plaintiff States and consumers could have purchased less expensive generic versions of Provigil beginning in 2006, saving hundreds of millions of dollars – if not more.

7. Defendants conduct to delay generic competition was illegal and anticompetitive in violation of the Sherman Antitrust Act and various state laws.

II. JURISDICTION AND VENUE

8. This Complaint alleges violations of Section 1 and Section 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, and seeks equitable relief as well as recovery of damages and injury to consumers under Section 4 of the Clayton Act, 15 U.S.C. § 15, and Section 16 of the Clayton Act, 15 U.S.C. § 26. This Court has jurisdiction over such claims pursuant to 28 U.S.C. §§ 1331 and 1337(a) and 15 U.S.C. §§ 15, 26. The Complaint also alleges violations of numerous state antitrust and consumer protection laws and seeks equitable relief as well as damages under these laws due to injury to Plaintiff States and their consumers resulting from Defendants' unlawful conduct. The Court has supplemental jurisdiction over such claims under 28 U.S.C. § §1332(d) and 1367 because these claims are so related to the federal claims that they form part of the same case or controversy.

9. Venue is proper within this district because Defendants transact business

within this district, and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this district. Venue, therefore, is appropriate within this district under 15 U.S.C. § 22, and 28 U.S.C. § 1391(b) and (c).

III. THE PARTIES

10. Plaintiff States are sovereign states or quasi-sovereign[1] entities that bring this action by and through their Attorneys General, and Offices of Attorneys General: (a) in their sovereign or quasi-sovereign capacities as representatives for the benefit of natural persons and/or as *parens patriae* of natural persons under state or federal law; (b) as *parens patriae* in their sovereign capacities to redress injury to their respective states' general economies; (c) in their proprietary capacities, which may include state departments, bureaus, agencies, political subdivisions, and other instrumentalities as purchasers (either directly, indirectly, or as assignees), based on purchases of Provigil; and/or (d) as the chief law enforcement agency of each state, in connection with their role to protect their respective state and its residents from exploitative and anticompetitive conduct as are alleged herein.

11. Defendant Teva Pharmaceutical Industries, Ltd. is an Israeli company with its principal executive offices listed at 5 Basel Street, P.O. Box 3190, Petach Tikva 49131, Israel. Upon information and belief, Teva Pharmaceutical Industries, Ltd is the world's largest generic pharmaceutical company, and markets several branded drugs as well.

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[1] References to the States as sovereign must be qualified with respect to the District of Columbia, which is not itself sovereign but does have governmental claims based on its "quasi-sovereign interest in the . . . well-being . . . of its residents in general." *See Alfred L. Snapp & Son, Inc. v. Puerto Rico*, 458 U.S. 592, 607 (1982) (applying analysis to Puerto Rico).

12. Defendant Teva Pharmaceuticals USA, Inc., a wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd., is a company incorporated under the laws of the State of Delaware, with its principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania 19454. Teva Pharmaceuticals USA, Inc. develops, manufactures, and markets pharmaceuticals and related products in the United States, including Provigil. Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc., will be collectively referred to herein as "Teva."

13. Defendant Cephalon is a company incorporated under the laws of the State of Delaware, with its principal place of business at 41 Moores Road, Frazer, Pennsylvania 19355. Cephalon develops, manufactures, and markets pharmaceuticals and related products in the United States, including Provigil. Cephalon has been a wholly-owned subsidiary of Teva since October 2011.

14. Defendant Barr is a company incorporated under the laws of the State of New York, with its principal place of business at Two Quaker Road, Pomona, New York 10970. Barr principally develops, manufactures and markets generic versions of brand name drugs. Barr has been a wholly-owned subsidiary of Teva since December 2008.

IV. FACTUAL BACKGROUND

A. The Governing Regulatory Background

15. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"), governs, *inter alia*, the manufacturing, sale, and marketing of pharmaceuticals in the United States. Pursuant to the FDCA, a company seeking to bring a new drug to market must submit a New Drug Application ("NDA") with the Food and Drug Administration ("FDA") and provide scientific data demonstrating that the drug is safe and effective for its intended use. 21 U.S.C § 355(b)(1). The process for filing and obtaining FDA approval of an NDA may be costly and time consuming.

16. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, commonly referred to as the Hatch-Waxman Act ("Hatch-Waxman" or "Act"), which was intended to encourage and facilitate competition from lower-priced generic drugs, while also providing further incentives for pharmaceutical companies to invest in new drug development. By creating benefits and incentives for both generic and branded pharmaceutical manufacturers, the Act reconciles the competing policy goals of rewarding innovation and expediting access to less expensive generic versions of important, but costly, branded drugs.

17. One means by which Hatch-Waxman expedites generic competition is by creating a simplified, quicker, and less costly process for obtaining FDA approval for generic pharmaceuticals. Under the Act, a company seeking to market a generic version of a drug that has already been approved pursuant to an NDA, may obtain FDA approval by filing an Abbreviated New Drug Application ("ANDA") and demonstrating that its generic version is

"bioequivalent" to the referenced, approved branded drug.[2] By permitting the generic applicant to rely on studies submitted by the NDA applicant (*i.e.*, the branded drug manufacturer), the Act significantly reduces generic drug development costs and speeds up the FDA approval process for generic drugs.

18. To reward generic competition, the Act grants generic exclusivity to the first ANDA(s) challenging all patents referencing the relevant branded drug. The first approved ANDA(s) are awarded 180 days of exclusivity, during which time FDA may not approve any other ANDA for the same drug. 21 U.S.C. § 355(j)(5)(B)(iv). This is typically referred to as "180-day exclusivity" or "First to File" exclusivity. In the case where multiple companies properly and simultaneously challenge all patents referencing the relevant branded drug, exclusivity can be shared.[3]

19. The Act and the FDCA also encourage innovation by branded drug companies, such as by extending exclusivity for specific efforts, *e.g.*, five years for a new chemical entity, seven years for treating rare diseases, and six months for conducting pediatric studies. As detailed below, Cephalon sought and obtained each of these exclusivity extensions, with the net effect of extending Provigil's exclusivity through December 2005.

20. The Act includes provisions benefitting branded drugs claiming patent protection. Thus, for example, a branded drug manufacturer may obtain up to a five-year patent extension to

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[2] A generic is "bioequivalent" to a branded drug when the rate and extent of absorption of the generic drug is not significantly different from the rate and extent of absorption of the branded drug, when administered at the same dosage. *See* 21 C.F.R. §320.1(a).

[3] *FDA Guidance for Industry: 180-day Exclusivity When Multiple ANDAs Are Submitted on the Same Day* (2003), available at http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm072851.pdf

compensate for lost time caused by the FDA regulatory approval process. 35 U.S.C § 156. In addition, the Act provides an expedited, simplified process for branded manufacturers to assert and resolve patent disputes with generic manufacturers. Under this process, a branded drug manufacturer includes in its NDA a list of all patents that it claims covers the drug for which it seeks approval and "with respect to which a claim of patent infringement could reasonably be asserted." 21 U.S.C. § 355(b)(1)(G). The FDA then publishes the claimed patents – without any independent review of the patents – in its "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book"), which is referenced by generic drug manufacturers.

21. Every generic drug manufacturer seeking FDA approval to market a generic version of a drug already approved by an NDA, must affirmatively disclose in its ANDA the effect of its proposed generic drug on any patents listed in the Orange Book. Specifically, the manufacturer in its ANDA must certify that either: (I) no patent information is listed in the Orange Book for the proposed generic drug; (II) the listed patents have expired; (III) the listed patents will expire before the generic product is marketed; or (IV) the patents listed are invalid or will not be infringed by the generic (referred to as "paragraph IV filings"). 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV).

22. If a branded drug manufacturer files an infringement action within 45 days after receiving notice of a Paragraph IV filing, FDA approval of the ANDA will be delayed. Specifically, in such cases, FDA must stay its final approval of the ANDA until the earliest of:

(1) patent expiration, (2) resolution of the patent litigation in favor of the generic company, or (3) the expiration of an automatic 30-month waiting period.[4]

23. Although FDA may grant "Tentative Approval" to an ANDA during the 30-month stay when it finds that "the generic drug satisfies the requirements for approval at the time of review, but final approval is blocked by a stay, a marketing exclusivity period, or some other barrier," *Astrazeneca Pharmaceuticals LP v. FDA*, 850 F. Supp. 2d 230,235 (D.D.C. 2012), an ANDA may not launch unless it has Final Approval.

B. Effects and Benefits of Generic Competition

24. Although therapeutically the same as its branded counterpart, the first AB-rated generic equivalent to a branded drug is typically priced significantly lower than the brand.[5] Upon the entry of additional AB-rated generic drugs, generic drug prices fall even more.

25. Because of these price advantages, almost all states and the District of Columbia encourage generic competition through laws that allow pharmacists to dispense an AB-rated generic drug when presented with a prescription for its branded equivalent, unless a physician directs, or the patient requests, otherwise. These state laws facilitate substitution of lower-priced AB-rated generic drugs for higher-priced branded drugs.

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[4] This was altered somewhat by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, but the changes do not apply to the Paragraph IV filings at issue in this litigation.

[5] A generic drug is considered "AB-rated" only if it is therapeutically equivalent (in addition to being bioequivalent) to its branded counterpart. This requires that the generic not only have the same active ingredient, clinical effect and safety profile as the branded drug, but also the same dosage form, strength, and route of administration.

26. Many third party payers of prescription drugs (including commercial insurers and state Medicaid programs) have adopted policies to encourage the substitution of AB-rated generic drugs for their branded counterparts.

27. As a result of lower prices and the ease of substitution, many consumers routinely switch from a branded drug to an AB-rated generic drug upon its introduction. Consequently, AB-rated generic drugs typically capture a significant share of their branded counterparts' sales, causing a significant reduction of the branded drugs' unit and dollar sales. Typically, when the branded manufacturer's exclusivity ends and multiple generic versions of the drug enter the market (as would be the case here), a branded drug loses approximately 90% of its market share within a year.

28. Competition from generic drugs generates large savings for consumers. According to a study commissioned by the Generic Pharmaceutical Association, generic drugs saved the U.S. health system $254 billion in 2014 alone, an average savings of nearly $5 billion per week.[6] According to an FDA study examining average retail drug prices between 1999 and 2004, entry of a second generic version of a drug reduced the average generic price to nearly half of the price of the branded drug, and entry of additional generic versions of a drug reduced prices to 20% of the branded price – in other words, an 80% discount.[7]

29. Generic competition allows consumers and agencies in Plaintiff States to purchase AB-rated generic versions of a branded drug at substantially lower prices. However,

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[6] Generic Pharmaceutical Association, *Generic Drug Savings in the U.S.* (2015), http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf

[7] FDA, *Generic Competition and Drug Prices* (Mar. 1, 2010), http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm.

until a generic manufacturer enters the market, there is no bioequivalent generic drug which competes with the brand name drug, and therefore, the brand name manufacturer can continue to profitably charge high prices without losing all, or even a substantial portion, of its branded drug sales. Consequently, brand name drug manufacturers have a strong interest to use anticompetitive tactics, such as those alleged, to delay the introduction of generic competition into the market.

C. Provigil and Efforts to Launch Generic Modafinil

30. Provigil promotes wakefulness and is used in the treatment of certain sleep disorders, including narcolepsy and shift work sleep disorder. The active ingredient in Provigil is modafinil.

31. Modafinil is a psychostimulant that enhances wakefulness but its pharmacological profile is significantly different than other drugs used to promote wakefulness, such as amphetamines and methylphenidate. Because of modafinil's unique properties relative to other drugs that promote wakefulness, it is considered to be the "gold standard" for the treatment of excessive sleepiness associated with sleep disorders.

32. Modafinil was first discovered by Laboratoire L. Lafon ("Lafon"), a French pharmaceutical company, in 1976. A drug product containing modafinil has been available in France since 1994.

33. In 1993, Cephalon obtained exclusive U.S. rights to modafinil from Lafon, and acquired Lafon outright in 2001.

34. Cephalon filed an NDA for Provigil in December 1996, and received FDA approval in December 1998. Cephalon commercially launched Provigil in the United States shortly after FDA approval.

35. Cephalon obtained three different types of FDA exclusivities for Provigil. First, because FDA concluded that modafinil constituted a new chemical entity ("NCE"), Cephalon received NCE exclusivity. Second, Cephalon obtained Orphan Drug exclusivity because Provigil has an FDA-approved indication for narcolepsy, a rare disorder. Due to NCE and Orphan exclusivities, FDA was prevented from approving a generic until December 24, 2005. In March 2006, after NCE and Orphan exclusivity expired, Cephalon obtained pediatric extension, granting an additional 180 days of FDA exclusivity, through June 24, 2006.

36. Until it finally faced generic competition in 2012, Provigil was a very profitable drug for Cephalon. Sales and revenues for Provigil grew substantially over the years and until generic entry. In 1999, annual Provigil sales in the U.S. were approximately $25 million. By 2011, however, sales of Provigil exceeded $1 billion, and the drug accounted for more than half of Cephalon's total consolidated net sales.

37. Because of Provigil's commercial success, several generic drug companies filed ANDAs seeking FDA approval to market an AB-rated generic version of Provigil. Specifically, on the same day in December 2002 (the earliest day permitted), Barr Laboratories, Ranbaxy, Teva, and Mylan ("Generic Manufacturers") each filed ANDAs with paragraph IV certifications. As a result, each was expected to share the statutory 180-days of generic exclusivity.

38. On March 28, 2003, Cephalon filed suit in the United States District Court for the District of New Jersey alleging infringement of its Provigil patent by the Generic Manufacturers.

39. Each of the Generic Manufacturers received Tentative Approval from the FDA for its generic version of Provigil before the drug's Orphan Drug exclusivity expired on December 24, 2005: Barr on January 7, 2004; Ranbaxy on February 18, 2004; Mylan on February 9, 2005; and Teva on December 16, 2005.

40. As detailed further below, absent Defendant's wrongful and exclusionary conduct, each of the Generic Manufacturers would have obtained Final Approval from FDA, and would have begun selling its generic version of Provigil – at prices significantly below the price of brand name Provigil – on or shortly after the expiration of Provigil's Orphan Drug exclusivity on December 24, 2005.

V. DEFENDANTS' ANTICOMPETITIVE CONDUCT

A. Cephalon Fraudulently Procured a Second Patent For Provigil

41. Cephalon obtained exclusive U.S. rights to modafinil in 1993. The composition patent for modafinil expired in 2001, and Cephalon expected generic competition for Provigil in 2006, once its FDA exclusivity expired.

42. So as to continue obtaining monopoly profits for Provigil after its composition patent expired in 2001, Cephalon submitted a second patent application for Provigil.

43. On October 6, 1994, Cephalon filed United States Application Serial No. 08,319,124 ("the '124 Application") titled "Acetamide Derivative Having Defined Particle

Size." The '124 Application narrowly claimed a very specific formulation of modafinil consisting of a specified distribution of small particles, as well as certain uses.

44. Cephalon knew that its patent application would not be granted for several reasons, including that Cephalon was not the inventor and because the claimed invention was not sufficiently novel over prior inventions. And in fact, its application was rejected by the patent examiner.

45. Despite knowing that the claimed invention in the '124 Application was not patentable, Cephalon intentionally made material omissions and misrepresentations to the PTO to overcome the examiner's rejections so that the patent would issue. Specifically, Cephalon:

- Intentionally misrepresented that it was the inventor, despite knowing that Lafon not only conceived of the invention, but developed, manufactured, and supplied Cephalon with the very embodiment of the invention that was produced to the PTO as a sample of the invention;

- Intentionally failed to disclose that Lafon provided Cephalon with modafinil product that embodied its claimed invention and that Lafon communicated to Cephalon knowledge and technical information about tests that it had previously performed which demonstrated that ground modafinil with smaller particle sized produced better dissolution rates. This information along with the product sent by Lafon made the claimed invention obvious and thus unpatentable;

- Intentionally failed to disclose that in 1993, Lafon shipped modafinil API and tablets to Cephalon and provided technical information about testing it had done on the benefits of smaller particle sizes. Cephalon made no modification to the product provided by Lafon, but still used it as a sample of an embodiment of its claimed invention to the PTO. Because of this prior disclosure and shipment of modafinil, Cephalon knew that its invention was not patentable because a product embodying all the claims of the invention was the subject of a commercial sale more than one year before the '124 Application was submitted.

46. Because the patent examiner relied on Cephalon's material omissions and misrepresentations, the patent was issued rather than rejected. Specifically, on April 8, 1997,

the '124 Application issued as United States Patent No. 5,618,845, subsequently re-issued in 2002 as U.S. Patent No. RE37,516 (Collectively referred to as the "Formulation Patent"). The Formulation Patent expired in April 2014.

47. By obtaining and enforcing the Formulation Patent, Cephalon was able to delay generic competition until well after its Orphan Drug exclusivity expired in December 2005 (and when generic competition was expected).

48. Due to Cephalon's material omissions and misrepresentations before the PTO, the Formulation Patent was found to be invalid and unenforceable. Specifically, on November 7, 2011, this Court ruled that the Formulation Patent was invalid, in part on the following basis:

- Cephalon was not the inventor of the Formulation Patent, in violation of 35 U.S.C. § 102(f);
- An embodiment of all the claims of the invention was subject to a commercial sale and supply agreement between Cephalon and Lafon more than one year before the filing of the patent application (October 6, 1994), in violation of 35 U.S.C. § 102(b);
- The claimed invention was "obvious" under 35 U.S.C. § 103, in light of: (a) contemporaneous knowledge of modafinil's properties and effectiveness in the treatment of narcolepsy prior to 1994; (b) general knowledge on the importance and role of particle size on dissolution rate and bioequivalence; and (c) Cephalon's receipt of modafinil product from Lafon prior to July 1993 along with specific technical information provided by Lafon on the results of its testing on the modafinil product relating to the effects of smaller particle sizes on modafinil solubility and dissolution rate; and
- The patent application "does not specify the particle size of the modafinil post-tabletting" and "does not provide sufficient information to allow a person skilled in the art to determine the particle size in the finished pharmaceutical composition as claimed," in violation of 35 U.S.C. § 112.

49. This Court also found in its November 7, 2011 decision that Cephalon made numerous intentional and material omissions and misrepresentations to the PTO "relating to Lafon's substantial role in Cephalon's claimed invention." Specifically, this Court stated:

> "I find that the complete concealment of another company's extensive involvement in the product which is the subject of the claimed invention definitively establishes Cephalon's deception by clear and convincing evidence. Further, in addition to concealing Lafon's role as manufacturer and supplier of the product being claimed in the patent, Cephalon affirmatively told the PTO that it had modified particle size when in fact it had done nothing whatsoever to change, modify or improve the modafinil it received from Lafon." *See Apotex v. Cephalon*, 06-cv-2768, 2011 WL 6090696 at * 27 (E.D. Pa. Nov. 7, 2011), *aff'd* 2012-1417 (Fed. Cir. Apr. 8, 2013).

50. Because this Court found that "but for [Cephalon's] omissions or misrepresentations, the PTO would not have issued the patent," it concluded that Cephalon committed inequitable conduct as a matter of law. *Id.* at *25-27. The Federal Circuit affirmed this Court's findings of fact and conclusions of law. *Apotex v. Cephalon*, 2013 LEXIS App. (Fed. Cir. 2013).

B. Cephalon Had the Fraudulently Procured Patent Listed in the FDA Orange Book and Filed Sham Litigation Against Generics for the Purpose of Delaying Generic Competition

51. Despite knowing that the Formulation Patent was invalid and only issued because of its own intentional and material omissions and misrepresentations to the PTO, Cephalon nonetheless had the Formulation Patent listed in the Orange Book in connection with Provigil.

52. Pursuant to the Act, a branded drug company must provide FDA with "the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with

respect to which a claim of patent infringement could reasonably be asserted." 21 U.S.C. § 355(b)(1)(G). Because Cephalon knew that the Formulation Patent was invalid and only issued as a result of its intentional and material omissions and misrepresentations to the PTO, it was not a patent "with respect to which a claim of patent infringement could reasonably be asserted" and thus was improperly listed on the Orange Book.

53. Nonetheless, Cephalon intentionally had the fraudulently procured Formulation Patent listed in the Orange Book because it knew that doing so would deter or at least delay competition. First, Cephalon knew that merely listing a patent in the Orange Book might deter a company from attempting to launch a generic before expiration of the Formulation Patent, because pursuant to the Act, in addition to obtaining FDA approval, launching a generic before patent expiration would require submitting a Paragraph IV filing and the likely risk of patent litigation.

54. Second, patent litigation with an ANDA filer seeking to launch an AB-rated generic version of Provigil would almost certainly have delayed generic entry for at least 30 months. Cephalon knew that given the substantial revenues for Provigil, listing of its Formulation Patent in the Orange Book would result in ANDAs submitting Paragraph IV certifications, triggering the 30-month stay of FDA approval upon Cephalon's timely filing of an infringement action. Cephalon also knew that patent litigation with ANDA filers could delay generic competition for even longer than 30 months because FDA is not required to grant Final Approval upon expiration of the 30-month stay. Rather, sometimes FDA waits to grant Final Approval of an ANDA until all patent issues are resolved – which may occur months to years after the 30 month stay expires.

55. And even if FDA were to grant Final Approval for an ANDA immediately after expiration of the 30-month stay (and during ongoing patent litigation), a generic company may nonetheless decide to delay launching its generic until all patent issues are resolved in its favor, so as to avoid the substantial risk of an injunction and damages for infringement. With appeals, this process could take years to complete. As a result, by merely listing the fraudulently procured Formulation Patent in the Orange Book and enforcing the patent thereafter, Cephalon was able to delay or deter generic competition for at least 30 months.

56. And Cephalon did in fact file litigation asserting infringement of its fraudulently procured Formulation Patent against all four Generic Manufacturers. Specifically, in March 2003, Cephalon filed sham litigation in the United States District Court for the District of New Jersey alleging that all four Generic Manufacturers infringed the Formulation Patent. Cephalon's suits were a sham because it knew the Formulation Patent was invalid and only issued due to its intentional and material omissions and misrepresentations made before the PTO. Nonetheless, Cephalon filed the infringement actions because it knew that doing so would delay generic competition.

57. Pursuant to the Act, Cephalon's filing of the four infringement actions against Mylan, Teva, Barr, and Ranbaxy triggered the 30-month stay of FDA approval for each of these ANDAs, thereby delaying FDA approval of generic modafinil.

C. Cephalon Pays off Generic Manufactures to Delay Generic Entry Until April 2012

(i) Cephalon Knew that its Patent Suit was a Sham and Thus Needed Additional Means of Delaying Generic Competition

58. Despite successfully (and illegally) extending its Provigil monopoly profits, Cephalon realized that generic competition was imminent upon expiration of Provigil's Orphan Drug exclusivity on December 24, 2005.

59. There were several indications before December 2005 that generic competition was imminent. First, there was no regulatory bar preventing the FDA from approving generic modafinil after December 2005. The statutory 30-month stays of FDA approval for the Generics Manufacturers (triggered by the filing of the sham litigations), as well as FDA exclusivities that Cephalon obtained for Provigil, all expired by December 2005.[8] Thus, FDA could have approved any or all of the ANDAs shortly after December 2005 – and such approval was likely given that each ANDA had received Tentative Approval from FDA by the end of 2005. Second, Cephalon knew that its Formulation Patent was invalid, and as a consequence, that it would likely lose its sham patent litigation. Third, *even if*, the Formulation Patent were somehow valid and enforceable, there was still a significant likelihood that one or more ANDAs would not infringe the patent given its narrow claims, which covered only a single formulation of modafinil. Indeed, a subsequent ANDA filed by Apotex was in fact found not to infringe the Formulation Patent. *See, Apotex v. Cephalon,* 06-cv-2768 (E.D.Pa. March 28, 2012).

[8] Although Cephalon received an additional 180 days of pediatric exclusivity on March 28, 2006, this would not have any effect on a generic that was approved and launched before that date.

60. In November 2005, Cephalon's management was so convinced that generic competition was imminent, that Cephalon informed the investment community that it projected a substantial reduction of Provigil sales in 2006 due to expected generic competition.

61. To delay the imminent generic competition for Provigil, Cephalon began negotiating settlements of the patent suits with the Generic Manufacturers in 2005. Cephalon's primary goal in these negotiations was to delay generic competition for Provigil for as long as possible.

62. Because Cephalon's patent infringement claims against the Generic Manufacturers were weak, Cephalon realized that the Generic Manufacturers would have to receive substantial value in order to induce them to forego their expected profits from sales of generic Provigil after Cephalon's exclusivity expired.

63. Moreover, to protect and maintain its monopoly profits in the modafinil market, Cephalon would have to induce each and every of the Generic Manufacturers to refrain from selling their generic versions of Provigil, because as a result of generic substitution laws and practices, *the entry of even a single generic product would quickly cause the majority of modafinil purchases to switch* from Cephalon's branded Provigil to the substantially less expensive – but bioequivalent – generic modafinil.

64. By early 2006, Cephalon settled all patent litigation with the four Generic Manufacturers. Each settlement included exclusionary large and unjustified "reverse" payments and side-deals. The side-deals, while often in separate contracts, were not independent business transactions, but were instead inextricably linked with the agreed-upon delayed generic entry date.

65. Cephalon provided an additional incentive to each of the four Generic Manufacturers to settle, by including an acceleration clause in each settlement and by publicizing that provision of each settlement. The clause allowed for accelerated entry by each of the Generic Manufacturers in the event that another generic company entered the market. The clause made continued litigation or launching-at-risk less attractive for each successive Generic Manufacturer because it would automatically permit each Generic Manufacturer to launch upon entry of any other generic competitor, thereby driving down the price of AB-rated generic version(s) of Provigil. The purpose and effect of Cephalon's agreements with the Generic Manufactures was to maintain Cephalon's Provigil monopoly and eliminate potential generic competition to Provigil until April 2012.

(ii) Cephalon's Anticompetitive Settlement with Teva

66. On December 8, 2005, Cephalon and Teva agreed to settle their patent litigation. Under this settlement, Teva agreed that it would not launch any generic version of Provigil before April 2012, unless another generic company launched a generic version of Provigil earlier than that date - in which case Teva also would be allowed to enter at that time. Cephalon and Teva publicized this accelerated entry agreement provision in press releases announcing the settlement.

67. The settlement agreement provided Teva with substantial compensation for its agreed-to delayed launch of generic Provigil. Specifically, Cephalon agreed to pay Teva up to $125 million in royalties based on Cephalon's worldwide sales of Provigil and successor products. Purportedly, these payments were made in exchange for a license to a patent and patent

application Teva held relating to modafinil. However, Cephalon did not need – and had no interest in licensing Teva's modafinil-related patent rights. Cephalon also agreed to purchase active pharmaceutical ingredient ("API") for Provigil from Teva at prices substantially higher than the price Cephalon paid to its existing supplier. The patent license and higher prices that Cephalon paid Teva were merely means by which Cephalon attempted to hide its exclusionary payment to Teva. The compensation that Cephalon agreed to provide Teva was designed to, and did, induce Teva to settle the Provigil patent litigation and agree to refrain from marketing generic Provigil until April 2012.

(iii) Cephalon's Anticompetitive Settlement with Ranbaxy

68. On December 22, 2005, Cephalon and Ranbaxy settled their patent litigation. Under this settlement, Ranbaxy agreed that it would not launch any generic version of Provigil before April 2012, unless another generic company launched a generic version of Provigil earlier than that date.

69. As with Teva, Ranbaxy would not agree to refrain from launching generic Provigil until after April 2012 unless it received substantial compensation. As with Teva, Cephalon agreed to provide Ranbaxy this compensation in the form of an API supply agreement and a license to a patent that Ranbaxy held for modafinil. The exclusionary payments to Ranbaxy were even more pretextual than Teva's since Ranbaxy did not (and does not) even manufacture modafinil API itself, but rather purchases it from a third party. However, the API agreement allowed Teva to compensate Ranbaxy by selling the API at an agreed-to substantial markup. Similarly, the $5 million fee that Cephalon agreed to pay to license Ranbaxy's modafinil patents was clearly pretextual, as Cephalon did not need such a license. The

compensation that Cephalon agreed to provide Ranbaxy under the settlement was designed to, and did induce, Ranbaxy to settle the Provigil patent litigation and agree to refrain from marketing generic Provigil until April 2012.

(iv) Cephalon's Anticompetitive Settlement with Mylan

70. On January 9, 2006, Cephalon and Mylan settled their patent litigation. Pursuant to the settlement, Mylan agreed that it would not launch any generic version of Provigil before April 2012, unless another generic company launched a generic version of Provigil earlier than that date.

71. As with Teva and Ranbaxy, Mylan required significant compensation in exchange for an agreement to refrain from competing until April 2012. To hide its exclusionary payment to Mylan, Cephalon entered into simultaneous product development deals with Mylan that provided Mylan a guaranteed minimum of at least $45 million. Prior to its agreement with Mylan, Cephalon had not sought the technology that Mylan contributed to the product development deals. Rather, the agreement and corresponding compensation provided by Cephalon to Mylan was designed to, and did, induce Mylan to settle the Provigil patent litigation and agree to refrain from marketing generic Provigil until after April 2012.

(v) Cephalon's Anticompetitive Settlement with Barr

72. On February 1, 2006, Cephalon settled patent litigation with Barr and Barr's partner, Chemagis, Ltd. (together with its affiliates, "Chemagis"). Under the settlement, Barr agreed that it would not launch any generic version of Provigil before April 2012, unless another generic company launched a generic version of Provigil earlier than that date.

73. As with the other Generic Manufacturers, Barr was unwilling to refrain from marketing generic Provigil until April 2012 absent substantial compensation. To satisfy Barr and Chemagis, and mask its exclusionary payments to them, Cephalon agreed to the following: (1) paying Barr $1 million for a license to a patent application that Barr held related to modafinil; (2) purchasing modafinil API directly from Chemagis (and indirectly from Barr via Barr's profit-sharing arrangement with Chemagis) at high markup prices; (3) paying Chemagis $4 million in exchange for a license to a patent and patent application that Chemagis held related to modafinil; and (4) paying Chemagis at least $20 million for two product development collaborations. The patent licenses and side-deals were merely means by which Cephalon attempted to hide its exclusionary payment to Barr and Chemagis. The compensation Cephalon agreed to provide Barr and Chemagis was designed to, and did, induce Barr and Chemagis to settle the Provigil patent litigation and agree to refrain from launching generic Provigil until after April 2012.

D. The Effects of Cephalon's Anticompetitive Agreements

74. Cephalon's settlement agreements with the Generic Manufacturers successfully delayed generic entry until April 2012, providing Cephalon with approximately six years of unlawful additional monopoly profits at the expense of purchasers of Provigil – including consumers and Plaintiff States. Indeed, settling the patent litigation with the Generic Manufacturers ensured that the anticompetitive effects were widespread, since *a finding of invalidity would have removed the patent as a barrier to generic entry for all* (not just the Generic Manufacturers).

75. The anticompetitive effects of the settlements were exacerbated due to their "bottleneck" feature, preventing *any* company – not just the Generic Manufacturers – from launching generic modafinil until April 2012. Because the Generic Manufacturers collectively shared First to File exclusivity, FDA was barred from approving *any* other generic version of Provigil until the 180-day exclusivity period expired. And only the commercial marketing of generic Provigil by at least one of the Generic Manufacturers or an appeals court decision declaring the Formulation Patent invalid or not infringed would trigger the 180-day exclusivity period. Cephalon settlements with all the Generic Manufacturers – all which agreed not to launch prior to April 2012 – thus ensured that the 180-day exclusivity would not be triggered until April 2012.

76. Finally, the breadth of the agreements also evinces their anticompetitive effects. Two of the settling Generic Manufacturers (Teva and Mylan) agreed not to develop, market, or sell generic versions of Provigil, but also agreed not to develop, market or sell generic equivalents of *successor products*. Similarly, the remaining settling Generic Manufacturers agreed to not sell generic products *whether or not they infringed the Formulation Patent.* In contrast, Cephalon's patent infringement suits had the potential to restrict only sales of Generic Manufacturers' proposed versions of generic Provigil (*i.e.* the version disclosed in their ANDAs to which FDA gave Tentative Approval).

77. By entering into broad settlement agreements that well exceeded the Formulation Patent's exclusionary rights and restricted Generic Manufacturers' ability to launch non-infringing, competing modafinil products, Cephalon was able to stifle competition for generic modafinil and harm Plaintiffs States and consumers who purchased Provigil for many years.

VI. Cephalon's Conduct Harmed Competition, Consumers, and Plaintiff States

78. Cephalon's enforcement of an invalid and fraudulently procured patent for Provigil created barriers to generic entry that were certain to deter and/or delay generic competition. Cephalon misused the very provisions of the Hatch-Waxman Act that were intended to *encourage* generic competition to instead *delay* it. Cephalon listed its fraudulently procured Formulation Patent in the Orange Book, knowing that it would likely deter generic entry. Thereafter, Cephalon filed suit against the Generic Manufactures, with the understanding and intent that its sham litigation would delay generic completion due to misusing the Act's 30-month stay of FDA approval for generics.

79. In order to favorably end its sham litigation, Cephalon negotiated settlements with each and all of the Generic Manufacturers so as to protect its invalid patent and ensure delayed generic entry. Cephalon realized that because the Generic Manufacturers collectively shared 180-day generic exclusivity, it would have to settle with each to effectively delay generic entry. Thus, by means of four separate settlements with each of the Generic Manufacturers, Cephalon was able to successfully delay generic competition for nearly six years, until April 2012.

80. And Cephalon's anticompetitive settlement agreements *prevented the possibility of generic competition from any source,* not just the settling Generic Manufacturers. As the Generic Manufactures collectively shared 180-day generic exclusivity, the settlements ensured that the 180-day generic exclusivity was not triggered until April 2012, preventing any possibility of generic competition from any source until at least then.

81. Entry of generic Provigil would have given Plaintiffs and consumers the choice between branded Provigil and lower-priced generic modafinil. Indeed, generic entry in early 2006 (as expected) would have quickly and significantly reduced Cephalon's sales of Provigil and led to a significant reduction in the average price that purchasers would have paid for generic Provigil. Plaintiffs and consumers would have saved hundreds of millions of dollars (or more) by purchasing generic versions of Provigil. Instead, via its anticompetitive conduct, Cephalon was able to retain those potential savings for itself (as well as use some to compensate the Generic Manufacturers for their agreement to delay launching generic Provigil).

82. Cephalon used various provisions of the Act to benefit itself, such as receiving extended exclusivity for Provigil. When these benefits were exhausted, Cephalon subverted other benefits of the Act – such as allowing consumers and Plaintiff States to enjoy the full benefits of generic competition. Cephalon listed its fraudulently procured Formulation Patent in the Orange Book, filed sham litigation against the Generic Manufacturers, and entered into anticompetitive settlement agreements. As a result, Cephalon swindled an additional six years of monopoly protection for Provigil. Through its scheme to prevent generic competition, Cephalon abused the Act's regulatory structure and violated the antitrust law at the expense of Plaintiff States and consumers, who were denied the full benefits of generic competition as a consequence of Cephalon's actions.

83. As purchasers of Provigil, Plaintiff States and consumers were harmed by Cephalon's anticompetitive conduct. Rather than having the option of buying less expensive generic modafinil, Plaintiff States and consumers were forced to pay monopoly prices for

Provigil for several additional years. As a result, Plaintiff States spent at least tens of millions of dollars more than they should have to enrich Defendants.

VII. Cephalon's Monopoly Power

84. Cephalon has exercised monopoly power in the United States with respect to Provigil. Direct evidence of this monopoly power includes Cephalon's ability to price Provigil substantially higher than the projected price of competing generic versions of Provigil and to exclude potential competitors by providing substantial compensation to delay competition.

85. Modafinil is its own relevant market. Although other drugs may be used to treat narcolepsy and the other sleep disorders for which Provigil is indicated, these drugs are distinct and thus their availability was not sufficient to prevent the anticompetitive effects of Cephalon's anticompetitive conduct to delay generic modafinil. Cephalon held a 100 percent share of the relevant market until April 2012.

86. All conditions precedent necessary to the filing of this action have been fulfilled, waived or excused.

COUNT I

Monopolization in Violation of Section 2 of the Sherman Act (Against Cephalon Only)

87. Plaintiff States repeat, and incorporates by reference, every preceding allegation above.

88. Cephalon's enforcement of a fraudulently procured patent violated Section 2 of the Sherman Act.

89. Despite knowing that the Formulation Patent was invalid and only issued due to its material misrepresentations and omissions to the PTO, Cephalon used it to maintain its modafinil monopoly after expiration of Orphan Drug exclusivity, when it expected generic entry and corresponding loss of Provigil profits.

90. By listing its fraudulently procured patent in the Orange Book and thereafter filing sham patent litigation against the Generic Manufacturers, Cephalon misused the Act's provision for the sole purpose of delaying generic competition.

91. As a result of Cephalon's enforcement of its fraudulently procured patent, generic competition was delayed by several years, forcing Plaintiff States and consumers to pay more than they would have paid for modafinil, absent Cephalon's illegal conduct. But for Cephalon's illegal conduct, competitors would have begun marketing generic versions of Provigil well before they actually did, and/or would have been able to market such versions more successfully.

92. If manufacturers of generic modafinil entered the market and competed with Cephalon in a full and timely fashion, Plaintiff States and consumers would have substituted lower-priced generic modafinil for the higher-priced brand name Provigil for some or all of their modafinil requirements, and/or would have received lower prices on some or all of their remaining Provigil purchases.

93. During the relevant time period, Plaintiff States and consumers purchased substantial amounts of Provigil. As a result of Cephalon's enforcement of its fraudulently

procured patent, Plaintiffs and consumers were compelled to pay, and did pay, artificially inflated prices for their modafinil requirements.

94. Cephalon's enforcement of its fraudulently procured Formulation Patent had the purpose and effect of delaying generic competition and constitutes monopolization of the market for modafinil in the United States, in violation of Section 2 of the Sherman Act, 15U.S.C. §2.

COUNT II

Restraint of Trade in Violation of Section 1 of the Sherman Act

95. Plaintiffs repeat and incorporate by reference every preceding allegation.

96. Beginning on or about December 9, 2005, Cephalon and each of the Generic Manufacturers entered into contracts in restraint of trade, the purpose and effect of which was to prevent the sale of generic version of modafinil in the United States until April 2012, thereby protecting Provigil from any generic competition for nearly 6 years.

97. By entering into these exclusionary contracts, Defendants have unlawfully conspired in restraint of trade and committed a violation of Section 1 of the Sherman Act, 15 U.S.C. §1. Defendants' agreements are anticompetitive agreements between actual or potential competitors, in violation of Section 1.

98. Plaintiff States and consumers have been injured in their business and property by reason of Defendants' unlawful agreements. Plaintiff States and consumers have paid more for their purchases of Provigil than they would have paid absent Defendants' illegal agreements and were prevented from substituting a cheaper generic for their purchases of the more expensive Provigil.